IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: ANDROGEL ANTITRUST LITIGATION (NO. II)	CASE NO. 1:09-MD-2084-TWT END-PAYOR CLASS ACTIONS Hon. Thomas W. Thrash, Jr.
FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FUND, on behalf of itself and all others similarly situated, Plaintiff, v. UNIMED PHARMACEUTICALS, INC. et al., Defendants.	CASE NO. 1:09-CV-2914-TWT
GEORGE STEVEN LEGRAND, on behalf of himself and all others similarly situated, Plaintiff, v. UNIMED PHARMACEUTICALS, INC. et al., Defendants.	CASE NO. 1:10-CV-2883-TWT

HEALTH NET, INC., on behalf of itself and all others similarly situated, Plaintiff, v. UNIMED PHARMACEUTICALS, INC., et al. Defendants.	CASE NO. 1:11-CV-0334-TWT

CONSOLIDATED AMENDED END-PAYOR CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

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a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates; 70

b. All governmental entities, except for governmental funded employee benefit plans; 70

c. All persons or entities who purchased AndroGel or its AB-rated generic equivalent for purposes of resale or directly from Defendants or their affiliates; 70

d. Fully insured health plans (i.e., Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members); 70

e. The judges in this case and any members of their immediate families. 70

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Plaintiffs Health Net, Inc. ("Health Net"), Fraternal Order of Police Fort Lauderdale Lodge 31 Insurance Trust Fund ("FOP") and George Steven LeGrand ("LeGrand") (collectively "Plaintiffs"), on behalf of themselves and all others similarly situated, hereby seek damages, other monetary relief, and equitable relief for violations of federal and state antitrust laws, state consumer protection laws, and state common law principles of unjust enrichment against Defendant Solvay Pharmaceuticals, Inc. ("Solvay") now known as AbbVie Products, LLC ("AbbVie"), Unimed Pharmaceuticals, Inc., ("Unimed") (Solvay, AbbVie and Unimed collectively referred to herein as "Solvay"), Watson Pharmaceuticals, Inc. ("Watson") now known as Actavis, Inc. ("Actavis") (Watson and Actavis collectively referred to herein as "Watson"), Par Pharmaceutical Companies, Inc. ("Par"), and Paddock Laboratories, Inc. ("Paddock") now known as Perrigo Company ("Perrigo") (Paddock and Perrigo collectively referred to herein as "Paddock") (Watson, Par and Paddock collectively referred to herein as "Generic Defendants")(all collectively "Defendants"). Plaintiffs allege as follows based on (a) personal knowledge; (b) the investigation of their counsel, including review of pleadings and court orders in patent infringement and other litigation concerning the conduct at issue in this action; and (c) information and belief:

I. SUMMARY OF THE CASE

1. This litigation challenges Defendants' unlawful exclusion from the market of low-cost AB-rated generic substitutes for the brand name prescription drug AndroGel. Faced with the threat of losing market exclusivity, Defendants engaged in a series of anticompetitive actions which precluded less expensive generic equivilents of AndroGel from entering the market and extended Solvay's monopoly on the sale of AndroGel at least through 2015, denying Plaintiffs and members of the proposed class access to lower cost generic alternatives.

2. AndroGel[1] is a brand name hormone replacement drug marketed by Solvay for topical use as a testosterone replacement therapy for males with a deficiency or absence of endogenous testosterone. The active ingredient in AndroGel is synthetic testosterone, which has not been under patent protection for decades. By 2006, AndroGel was Solvay's top-selling product, with U.S. annual sales in excess of $400 million.

3. Defendants engaged in a scheme to delay entry of AB-rated generic equivalents in order to extend Solvay's monopoly on the U.S. market for brand name AndroGel. Among other actions, Solvay: (a) wrongfully obtained and listed Patent No. 6,503,894 (the "formulation patent" or "'894 patent") in the Food &

[1] All references to "AndroGel" herein are references to AndroGel 1.0%.

Drug Administration ("FDA") publication entitled Approved Drug Products with Therapeutic Equivalence evaluations (commonly referred to as the "Orange Book"); (b) filed and maintained baseless "sham" litigation against prospective generic competitors in order to obtain automatic 30-month stays under the Hatch-Waxman amendments to the Food, Drug and Cosmetic Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman"), preventing the FDA from granting final approval to those companies seeking to sell bioequivalent generic versions of AndroGel.[2] Defendants Solvay, Watson and Par/Paddock also entered into anticompetitive agreements whereby Solvay agreed to pay the Generic Defendants millions of dollars, as well as other compensation, in exchange for their agreement not to sell their AB-rated generc version of AndroGel at least until 2015. During this period of exclusivity Solvay then converted existing and future sales of AndroGel to its new low volume product, AndroGel 1.62%, so that any AB-rated generic AndroGel product that might eventually be introduced would not be substitutable.

4. But for these unlawful actions, Watson, and/or Par/Paddock would have begun marketing a generic AndroGel product far sooner than August 2015,

[2] Plaintiffs include allegations in this Consolidated Amended Class Action Complaint relating to antitrust violations steming from listing of the '894 patent in the Orange Book and on sham litigation solely to preserve any appealable issues arising from this Court's Corrected Opinion and Order dated October 30,2012 [Dkt. No. 849]. Plaintiffs do not seek to now adjudicate claims arising from allegation of sham litigation which were the subject of the Court's order.

and prior to the time Solvay was able to convert sales of AndroGel to its AndroGel 1.62% product.

5. By their conduct, Defendants have (a) restrained, suppressed and eliminated competition in the AndroGel market at least through 2015, if not indefinitely; (b) maintained an unlawful monopoly in the AndroGel market, and (c) conspired to allocate amongst themselves 100% of the market for AndroGel, all in violation of state and federal antitrust laws, state consumer protection statutes, and state common law principles governing unjust enrichment.

6. Defendants' unlawful monopoly allows Solvay to charge supracompetitive prices for AndroGel causing Plaintiffs and members of the proposed Class to be overcharged by many millions of dollars on AndroGel purchases made during the foreclosure period.

7. As a direct and proximate result of Defendants' conduct, consumers and third-party payors throughout the United States have been denied the benefits of free and unrestrained competition in the AndroGel market. Specifically, purchasers have been denied the opportunity to choose between the AndroGel brand name prescription product and one or more AB-rated generic versions of the medication, which would have been priced well below AndroGel's supracompetitive prices.

II. JURISDICTION AND VENUE

8. This Court has jurisdiction over this action pursuant to the Class Action Fairness Act of 2005 ("CAFA"), 28 U.S.C. § 1711, et seq., which vests original jurisdiction in federal district courts for any multi-state class action where the aggregate amount in controversy exceeds $5,000,000 and the citizenship of any member of the class of plaintiffs is different from any defendant. The diversity and amount in controversy requirements of CAFA are satisfied in this case.

9. Defendants reside, transact business, are found, and/or have agents in this district, and the interstate trade and commerce, described within, is carried out, in substantial part, in this district. Furthermore, related actions have been transferred to this district pursuant to an Order of the Judicial Panel on Multidistrict Litigation. Venue is therefore proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and 15 U.S.C. § 22.

III. THE PARTIES

10. Plaintiff Health Net, Inc. ("Health Net" or "Plaintiff") is a welfare benefit plan with its principal place of business in Woodland Hills, California. Health Net represents participants who have family medical coverage and purchased or paid for AndroGel during the Class Period other than for resale and were injured by the illegal conduct alleged herein. Health Net sustained injury

when it purchased and/or provided reimbursement for AndroGel purchases made in each of the fifty states and Puerto Rico between February 1, 2006 and the present.

11. Plaintiff FOP is a health and benefit fund operated for the benefit of present and retired workers of the union and their families. FOP was established pursuant to a duly executed Trust Agreement for the purpose of providing health benefits, including prescription benefits to its defined beneficiaries. FOP maintains its principal place of business in Fort Lauderdale, Florida and, thus, is a citizen of Florida. FOP sustained injury when it purchased and/or provided reimbursement totaling more than $54,000 for AndroGel purchases made in Florida, Georgia, Ohio, and Tennessee between November 1, 2004 and the present.

12. Plaintiff LeGrand is an adult individual residing in West Hollywood, California who sustained injury when he paid for more than $2,700 for AndroGel in California between January 19, 2009 and the present.

13. At all relevant times, Defendant Unimed Pharmaceuticals, Inc. was a wholly-owned subsidiary of Defendant Solvay Pharmaceuticals, Inc. On or about February 16, 2010, Abbott Laboratories, Inc. acquired Solvay. On or about January 1, 2013, Abbott Laboratories, Inc. spun off its pharmaceutical business to Defendant AbbVie, Inc., a Delaware corporation with its principal place of

business at 1 North Waukegan Road, North Chicago, Illinois 60064. Abbvie Products, LLC is a wholly-owned subsidiary of AbbVie, Inc.

14. At all relevant times, Solvay was, and now AbbVie is, engaged in the distribution and sale of branded pharmaceutical products, including AndroGel. Solvay negotiated and/or approved Unimed's relevant unlawful agreements concerning AndroGel, the filing and maintenance of sham litigation against Paddock and Watson, and has a financial interest in AndroGel.

15. Defendant Watson Pharmaceuticals, Inc. is now known as Actavis, Inc. Watson acquired Actavis in October, 2012. Watson changed its name to Actavis after the acquisition. Actavis, Inc. is a Nevada corporation with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey. At all relevant times, Watson (now Actavis) has principally been in the business of developing, manufacturing and marketing generic versions of brand name drugs.

16. Par is a Delaware corporation with its principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey. Par principally develops, manufactures and markets generic versions of brand name drugs.

17. Defendant Paddock Labratories is now known as Perrigo Company. Perrigo Company acquired Paddock's assets in January, 2011. Perrigo is a

Michigan corporation with its principal place of business at 515 Eastern Avenue, Allegan, Michigan. Paddock's principal business is developing, manufacturing and marketing generic versions of brand name drugs.

IV. LEGAL BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand Name Drugs

18. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 ("FDCA"), a manufacturer of a new drug must obtain approval from the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

19. In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman"). The purpose of Hatch-Waxman was to hasten the delivery of inexpensive generic drugs to the market while respecting the patent rights of brand name drug patent holders.

20. Hatch-Waxman eliminates the need for generic manufacturers to file a lengthy and costly NDA to obtain FDA approval for generic substitutes. Under Hatch-Waxman, the generic manufacturer is permitted to file an abbreviated

application, or ANDA, that (a) incorporates the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, and (b) shows that the proposed generic drug is bioequivalent to the brand name drug, i.e., that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug.

21. Once bioequivalence is demonstrated, the FDA assigns an "AB" rating to the generic drug, permitting it not only to be sold, but also to be substituted (and in some instances, required to be substituted) for the brand name drug at the pharmacy counter.

22. To protect brand name manufacturers' ability to enforce their patents against infringement through the ANDA process, Hatch-Waxman also streamlined the patent enforcement process, providing that the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand name drug for up to 30 months if the patent holder initiated a patent infringement lawsuit against the ANDA applicant.

23. When the FDA approves a brand name manufacturer's NDA, Hatch-Waxman allows the brand manufacturer to list in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book," any patents that the brand manufacturer believes could

reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents.

24. The FDA plays only a ministerial role in Orange Book listings. The FDA relies completely on the brand name manufacturer for information concerning the validity of the patents and applicability of the patents to the brand name drug. The FDA does not check the representations supplied by the brand name manufacturer independently for accuracy or trustworthiness. After the NDA is approved, the brand name manufacturer may list other new patents in the Orange Book related to the NDA, if the name brand manufacturer certifies, among other things, that the new patents claim either the approved drug (for compound patents) or that the patents claim the approved drug for approved methods of use (for method-of-use patents). The NDA holder is required to list any new patents within 30 days of issuance. 21 U.S.C. §§ 355 (b)(1) & (c)(2). If the NDA holder does not do so, it cannot invoke the 30-month stay under Hatch-Waxman by suing on the late listed patent.

25. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the

Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

26. If a generic manufacturer files Paragraph I or II certifications, the FDA must act on the application within 180 days of receipt. If a generic manufacturer files a Paragraph III certification, the FDA can proceed with the ANDA approval process, granting final approval after the expiration of the applicable patents.

27. If a generic manufacturer files a Paragraph IV certification, however, a brand name manufacturer may delay the final FDA approval of the ANDA by suing for patent infringement. Specifically, if the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA may not grant

final approval to the ANDA until the earlier of (a) the passage of 30 months or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. During the pendency of the 30-month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would qualify for final approval but for the 30-month stay. The FDA, however, cannot authorize the generic manufacturer to go to market. Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification regarding the listed patent, a brand name drug manufacturer may delay the date of final approval and entry into the market of the generic drug.

28. As an incentive to spur generic companies to alter alternatives to brand drugs, the Hatch-Waxman Act gives the first generic company filing an ANDA containing a paragraph IV certification a period of protection from competition with other generic versions of the drug. If the first paragraph IV filing for the drug was made before December 2003, as it was here, the FDA may not approve other generic versions of the same drug until 180 days after the earlier of the date on which (a) the first company begins commercial marketing of its generic version of the drug or (b) an appeals court finds the patent(s) claiming the branded drug invalid or not infringed. This is referred to as "180-day exclusivity."

29. Because of the FDA rules alleged above, brand name manufacturers have an incentive to (a) list patents in the Orange Book, even if such patents are not eligible for listing; and (b) sue any generic competitor that files an ANDA with Paragraph IV certifications, even if the competitor's product does not infringe the listed patent(s), in order to delay final FDA approval of an ANDA for up to 30 months.

B. Brand Name Manufacturers Game the Regulatory Structure

30. Because the Hatch-Waxman regulatory scheme automatically delays approval of an ANDA whenever a brand name manufacturer sues the potential generic competitor for patent infringement, brand name manufacturers frequently take aggressive positions in listing patents in the Orange Book, and then bring patent infringement lawsuits against any generic competitor that files an ANDA with a Paragraph IV certification. Brand name manufacturers often sue generics simply to delay generic competition, rather than to enforce valid patents against infringing products.

31. In connection with the resolution of patent litigation arising out of Paragraph IV certifications, brand name manufacturers have also developed a practice of entering into "settlements" in which a brand name manufacturer pays off its generic competitors in exchange for a delay in generic competition. These

exclusion payment agreements are commonly known as "pay-for-delay agreements" or "reverse payment settlements."

32. Brand and generic manufacturers execute exclusion payment agreements as purported settlements of patent infringement lawsuits that brand manufacturers file against generic manufacturers. Initially these agreements took the form of a straight cash payment from the brand name manufacturer to the generic competitor. As a result of regulatory scrutiny and congressional investigations, brand name manufacturers and generic competitors have entered into increasingly elaborate agreements in an attempt to mask the fundamentally anticompetitive character of their agreements. Because the profits to be gained by delaying generic competition are so great, however, drug manufacturers retain the incentive to enter into such agreements.

33. The first generic filer's agreement to delay marketing its drug may also prevent other manufacturers of generics from bringing their own products to market. If the first-filed generic manufacturer is eligible for 180-days of marketing exclusivity; no other generic manufacturer can enter the market until the end of the exclusivity period. This "bottlenecking" tactic is known as exclusivity "parking."

34. In addition, brand and generic manufacturers can structure their settlements in a way that grants 180 days of exclusivity to the generic even where

it is likely that the generic has forfeited that exclusivity under one of the applicable forfeiture provisions of the Medicare Prescription Drug Improvement and Modernization Act of 2003, e.g., the failure to obtain tentative approval within 30 months of submitting a substantially complete ANDA. This results in a windfall to the generic and a subversion of the regulatory scheme. Because FDA will not typically make a formal 180-day exclusivity determination until another generic applicant has received final approval and is ready to launch, settlements that retain de facto exclusivity – even where it should be forfeit under the MMA – dissuade subsequent generic applicants from trying to obtain a court judgment of invalidity and/or infringement that would trigger the start of the 180 day period; because the lion's share of the generic revenues will perceivably go to the first filer, subsequent filers have less incentive to litigate to judgment.

C. No-Authorized-Generic Agreements

35. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period. Such an "authorized generic" is chemically identical to the brand drug, but is sold as a generic product through either the brand manufacturer's subsidiary (if it has one) or through a third-party generic manufacturer. Competition from an authorized generic during

the 180-day exclusivity period substantially reduces the first-filer's revenue, and substantially reduces drug prices for consumers.

36. In its recent study, Authorized Generic Drugs: Short-term Effects and Long-Term Impact (August 2011) (the "FTC Study"), the Federal Trade Commission ("FTC") found that authorized generics capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first filer; and (2) the presence of an additional generic in the market causes prices to decrease.

37. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, consumers and other drug purchasers such as Plaintiffs and the Class benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

38. Given the significant negative effect of an authorized generic on the first-filing generic's revenues, a brand manufacturer's agreement not to launch an authorized generic has tremendous value to the generic manufacturer. Brand

manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements deprive consumers and other drug purchasers such as Plaintiffs and the Class of the lower prices resulting from two forms of competition: (1) among the branded and the generic products; and (2) between the generic products.

39. Agreements not to compete with an authorized generic can take many forms. According to the FTC Study, one such form includes agreements whereby the brand manufacturer agrees to exclusively supply the first-filing generic with the authorized generic product. The result is no competition between an authorized generic and the first-filing generic's product for a period of time.

D. The Benefits of Generic Drugs

40. AB-rated generic versions of brand name drugs contain the same active ingredient, and are found by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between brand name drugs and AB-rated generics is price. Generics typically cost at least 30 percent less than their brand counterparts when there is a single AB-rated generic competitor and as much as 80 to 90 percent less when there are multiple AB-rated generic competitors on the market. As a result, AB-rated generics constitute both (a) an opportunity for drug purchasers and consumers to obtain enormous savings and

(b) a serious threat to the monopoly power and profits of the manufacturer of the brand name drug facing generic competition. Indeed, generics often take 90 percent of the sales from the brand name manufacturer within a year of entry.

41. The dollar value of a brand drug's sales typically decreases upon market entry of an AB-rated generic. This is because purchasers of the drug purchase the less expensive AB-rated generic rather than the more expensive brand name drug. For example, a drug like AndroGel, with annual sales of $400 million prior to generic competition, will see the dollar value of the drug's sales (assuming the number of prescriptions remains the same) drop to under $100 million within a year following generic entry. This is because pharmacists will substitute the less expensive AB-rated generic when filling prescriptions for the brand name drug. While this drop in cost allows purchasers to save a significant amount on prescriptions for the drug, it also presents a strong financial incentive for branded manufacturers to delay generic entry unilaterally or even collude with generic manufacturers to keep generics off the market and split the savings that purchasers would have enjoyed (in this example $300 million annually) among themselves.

42. A 1998 Congressional Budget Office Report estimated that in 1994 alone, purchasers saved $8 to $10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of their brand name counterparts. A 2004 FDA

study calculated that patients could reduce the daily costs of their medications by more than 50 percent by purchasing generic drugs when available. And, according to the National Association of Chain Drug Stores, the average retail price for a brand-name prescription was about $119 in 2007, while the average retail price for a generic prescription was about $34—a savings of over 70 percent.

43. Significant consumer savings can result when generic companies successfully challenge patents and enter the market prior to patent expiration. Indeed, empirical studies have shown that when pharmaceutical patent infringement claims are tested in court, the alleged infringer prevails in the majority of cases. An analysis of Federal Circuit decisions from 2002 through 2004 in which courts made final rulings on the merits of pharmaceutical patent claims (validity, infringement, or enforceability) found that alleged infringers had a success rate of 70 percent. An FTC study of all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and Paragraph IV generic applicants found similar results: when cases were litigated to a decision on the merits, the generic applicants prevailed 73 percent of the time. Thus, generic entry, even if achieved only a year or two before claimed patents expire, can result in billions of dollars in savings to consumers.

44. Until a generic manufacturer enters the market, there is no bioequivalent generic drug that can substitute for the brand name drug, and therefore the brand name manufacturer can charge supracompetitive prices profitably without material loss to sales volume. Consequently, brand name drug manufacturers have a strong interest in delaying the introduction of generic competition into the market.

45. Although therapeutically the same as its branded counterpart, the first AB-rated generic equivalent to a branded drug is priced lower than the brand. Upon the entry of additional AB-rated generic drugs, generic drug prices fall even more.

46. Because of these price advantages and other institutional features of the pharmaceutical market, states encourage generic competition through laws that allow (and in some states, require) pharmacists to dispense an AB-rated generic drug when presented with a prescription for its branded equivalent, unless a physician directs or the patient requests otherwise. These state laws facilitate substitution of lower-priced AB-rated generic drugs for higher-priced branded drugs.

47. Many third party payors of prescription drugs (health insurance plans and Medicaid programs, for example) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts.

48. As a result of lower prices and the ease of substitution, consumers routinely switch from a branded drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically capture a significant share of their branded counterparts' sales, causing a significant reduction of the branded drugs' unit and dollar sales.

V. FACTUAL BACKGROUND

A. Solvay's AndroGel Prescription Drug

49. Solvay markets a branded prescription drug called AndroGel. AndroGel is a pharmaceutical gel containing synthetic testosterone. Testosterone was first artificially synthesized in 1935 and has been available in various drug products since the 1950s. Pharmaceutical gel products like AndroGel have been available for decades.

50. In August 1995, Solvay licensed the U.S. rights to the testosterone gel formulation used for AndroGel from the Belgian pharmaceutical company Besins Healthcare S.A. (together with its affiliates, "Besins"), which had developed the

formulation. At the same time, Besins agreed to provide commercial supply of AndroGel to Solvay after the FDA approved the product for sale.

51. Solvay filed a U.S. New Drug Application for AndroGel in April 1999, which the FDA approved in February 2000. AndroGel is approved for testosterone replacement therapy in men with low testosterone. Low testosterone is often associated with advancing age, certain cancers, diabetes, and HIV/AIDS, among other conditions, and can result in fatigue, muscle loss, and erectile dysfunction.

52. AndroGel has consistently been Solvay's highest-selling pharmaceutical product. From 2000 through 2007, cumulative U.S. sales of AndroGel totaled over $1.8 billion. In 2007 alone, U.S. sales of AndroGel exceeded $400 million, representing one-third of Solvay's U.S. pharmaceutical revenue.

53. Solvay sells AndroGel at prices far above Solvay's cost of obtaining the product from Besins, making AndroGel highly profitable for Solvay. Even accounting for other direct expenses Solvay allocates to selling and marketing AndroGel, Solvay's profit margin on AndroGel net sales is substantial.

B. Solvay's Prosecution of the '894 Patent

54. On August 30, 2000, five years after Solvay licensed AndroGel from Besins, Solvay and Besins employees applied for a U.S. patent relating to AndroGel. The patent did not claim synthetic testosterone itself or methods of using testosterone generally, but rather covered the use of particular pharmaceutical gel formulation containing testosterone and other specified ingredients in specified amounts.

55. As described in a report by the United States Government Accountability Office, patent examiners are generally expected to process an average of 87 patent applications per year and have time quotas of a total of 19 hours to process each application from its filing through its final acceptance or rejection. These time quotas are reinforced by examiners' bonus compensation, which is largely tied to the number of applications processed to completion. The patent application process is an ex parte process in which patent examiners rely upon the information and candor of applicants. Thus, the vast majority of all patent applications are ultimately granted.

56. In prosecuting the patent application relating to AndroGel, Solvay submitted to the patent examiner multiple disclosure statements identifying more than 400 articles and patents discussing previous testosterone and hormone

therapies, together with copies of each of these articles and patents in multiple notebooks, comprising more than three feet of materials for the examiner to attempt to review. In addition, Solvay filed more than 240 additional pages of papers, responses, amendments, and declarations.

57. The patent Solvay prosecuted issued on January 7, 2003 as Patent No. 6,503,894 (the "formulation patent" or "'894 patent"). The patent is directed to pharmaceutical compositions containing testosterone gel formulations and methods of using these compositions to treat hypogonadism.

58. None of the originally filed claims in Solvay's patent application recited sodium hydroxide, whose chemical symbol is "NaOH."

59. Indeed, the sole reference to sodium hydroxide in the entire specification appears in Table 5 (reproduced below), which discloses a single formulation have a specific amount (4.72 grams) of a specific sodium hydroxide solution (0.1 N NaOH).

TABLE 5

Composition of AndroGel®

SUBSTANCE	AMOUNT (w/w) PER 100g OF GEL
Testosterone	1.0g
Carbopol 980	0.90g
Isopropyl myristate	0.50g
0.1 N NaOH	4.72g
Ethanol (95% w/w)	72.5g

Purified water	100.0g

Nowhere did the patent application disclose the concept of a range of sodium hydroxide concentrations in the pharmaceutical formulation.

60. The phrase "0.1 N" indicates that the sodium hydroxide is in a dilute aqueous solution (roughly 4 grams of sodium hydroxide per 1000 grams of solution), as opposed to the pure (anhydrous) form of sodium hydroxide. 4.72 grams of a 0.1 N NaOH solution contains approximately 0.019 grams of sodium hydroxide and approximately 4.70 grams of water. Thus, the overall concentration of sodium hydroxide concentration in the AndroGel formulation described in Table 5 was roughly 0.019 percent (0.019 grams in a total of 100 grams of formulation).

61. On October 29, 2001, Solvay filed an Amendment with the PTO that cancelled certain originally-filed claims and added others. New dependent claims 45 and 64 recited sodium hydroxide. In both of these new dependent claims, the term "sodium hydroxide" appears alone without any indication of either (a) a range (e.g., "about 1% to about 5%") or (b) a modifier indicating that the recited amount reflected the weight of a dilute solution (e.g., "0.1 N") rather than the weight of pure (anhydrous) sodium hydroxide. The remarks in Solvay's submission did not mention either these dependent claims or sodium hydroxide.

62. On December 20, 2001, Solvay filed a Supplemental Amendment, cancelling dependent claims 45 and 64 and adding new claims. Neither the new claims nor the applicants' remarks mentioned sodium hydroxide.

63. On February 2, 2002, Solvay filed a Second Supplemental Amendment. Among other things, the Second Supplemental Amendment changed all independent claims (except for one) to recite weight ranges for pure (anhydrous) sodium hydroxide, i.e., "about 1% to about 5%" and "about 1% to about 3%." None of those proposed claims referred to the weight ranges as referring to a dilute solution (i.e., 0.1 N). As support for these claims, Solvay cited Table 5 and stated: "Note that 4.72g of 0.1 NaOH = 1.8g NaOH in 100g of gel, or about 1.8%." By making that statement—i.e., by converting the 4.72 grams of a 0.1 N solution of sodium hydroxide in AndroGel to a measure of pure (anhydrous) sodium hydroxide—Solvay demonstrated its intent to express the sodium hydroxide limitation in the claims as pure sodium (anhydrous) hydroxide rather than as a 0.1 N solution. The remarks did not otherwise mention sodium hydroxide.

64. While the 1.8g NaOH in 100g of gel is within the ranges of "about 1% to about 5%" and "about 1% to about 3%" recited in the then newly-added claims,

there was no other calculation involving sodium hydroxide supplied by Solvay supporting this range.

65. Significantly, the calculation converting the 4.72g of 0.1 NaOH to its equivalent amount in pure form in the AndroGel composition was in error by a factor of roughly 100. That is, the equivalent amount of pure sodium hydroxide in the AndroGel composition in Table 5 is not 1.8 grams, but rather about 0.018 grams, per 100 grams of gel.

66. Subsequent to filing the Second Supplemental Amendment, Solvay further amended the claims reciting sodium hydroxide on two separate occasions, but on neither occasion did Solvay seek to amend the claims to recite the ranges for sodium hydroxide in a solution by inserting "0.1 N" or the like.

67. As a result of Solvay's prosecution of the patent: (a) the specification of the '894 patent application provides no written description support for any range of concentrations of sodium hydroxide (whether pure or in solution), and the sole mention of sodium hydroxide is a single concentration in a single formulation as reflected in Table 5; and (b) when claims were later added reciting ranges of sodium hydroxide—additions for which there was absolutely no written description support—those ranges indisputably referred to ranges of amounts of

pure (anhydrous) sodium hydroxide rather than ranges of amounts of a dilute sodium hydroxide solution such as 0.1 N.

68. On January 7, 2003 the '894 Patent issued. The five independent claims (i.e., claims 1, 9, 10, 18, and 31) recite:

> 1. A pharmaceutical composition, consisting essentially of:
>
> a. about 0.5% to about 10% testosterone;
> b. about 30% to about 98% alcohol selected from the group consisting of ethanol and isopropanol;
> c. about 0.1% to about 5% isopropyl myristate;
> d. about 1% to about 5% sodium hydroxide; and
> e. about 0.1% to about 5% of a gelling agent,
>
> wherein the percentages of components are weight to weight of the composition.
>
> 9. A hydroalcoholic gel formulation, consisting essentially of:
>
> a. about 1% to about 2% testosterone;
> b. about 50% to about 75% ethanol;
> c. about 0.5% to about 2% isopropyl myristate;
> d. about 1% to about 3% sodium hydroxide;
> e. about 0.5% to about 2% polyacrylic acid; and
> f. water in an amount sufficient to make the formulation 100%;
>
> wherein the percentages of components are weight to weight of the formulation.
>
> 10. A unit dose packet comprising inner and outer surfaces, and a pharmaceutical composition inside the packet, the composition consisting essentially of:
>
> a. about 0.5% to about 5% testosterone;
> b. about 30% to about 98% ethanol;
> c. about 0.1% to about 5% isopropyl myristate;

d. about 1% to about 5% sodium hydroxide; and
e. about 0.1% to about 5% of a gelling agent;
wherein the percentages of components are weight to weight of the composition.

18. A method for administering an active agent to a human subject in need thereof, the method comprising:

a. providing a phannaceutical [sic] composition consisting essentially of:
(i) about 0.5% to about 5% testosterone;
(ii) about 0.1% to about 5% of a gelling agent;
(iii) about 0.1% to about 5% isopropyl myristate;
(iv) about 1% to about 5% sodium hydroxide; and
(v) about 30% to about 98% alcohol selected form the group consisting of ethanol and isopropanol;
wherein the percentages are weight to weight of the composition; and

b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject so as to achieve a serum concentration within a range between about 300 ng testosterone per dl serum to about 1050 ng testosterone per dl serum within at least about 36 hours of daily dosing of the composition.

31. A method for administering an active agent to a human subject in need thereof, the method comprising:

a. providing a pharmnaceutical [sic] composition consisting essentially of:
(i) about 0.5% to about 5% testosterone;
(ii) about 0.1% to about 5% isopropyl myristate;
(iii) about 30% to about 98% of an alcohol selected from the group consisting of ethanol and isopropanol; and
(iv) about 0.1% to about 5% of a gelling agent;

wherein the percentages are weight to weight of the composition; and

b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject wherein serum concentration is substantially maintained between about 400 ng testosterone per dl serum to about 1050 ng testosterone per dl serum for at least 24 hours after the subject has applied the daily dose of the composition for at least 2 consecutive days.

Thus, each of claims 1,9,10 and 18 specify that pure sodium hydroxide accounts for at least "about 1%" sodium hydroxide on a "weight to weight basis."

69. In order to invoke the Hatch-Waxman 30-month stay, Solvay was required to list the patent within 30 days of issuance. Within 30 days of the issuance of the '894 Patent in January 2003, Solvay submitted it for listing in the Orange Book, along with a declaration signed under oath, certifying that one or more of the issued claims covered AndroGel, or an approved method of using AndroGel, and that the '894 Patent could reasonably be asserted against a person who engaged in the unauthorized manufacture, use, or sale of AndroGel.

70. The '894 formulation patent expires in August 2020. In addition, Solvay recently received regulatory exclusivity from the FDA based on pediatric studies that would provide Solvay with an additional six months of exclusivity beyond the expiration of its patent, through February 2021.

C. Solvay Seeks a "Certificate of Correction"

71. Five months after the patent issued, on or about June 12, 2003, Solvay requested that the PTO "correct" many claims of the '894 formulation patent. As Solvay knew, the '894 patent as issued did not cover the AndroGel product or likely generic equivalents that would be proposed in ANDAs filed with the FDA. This was because, like the FDA-approved AndroGel product, proposed generic products would not, and Watson and Paddock's generic versions of AndroGel did not, contain the concentration levels of pure sodium hydroxide required by the relevant claims of the '894 patent. Solvay knew that the compositions claimed in the relevant claims of the '894 patent would not be marketed by generic manufacturers because, as issued, the composition would be too caustic to be used on human skin. Generic manufacturers would seek to market an AB-rated equivalent of Solvay's AndroGel, which contained lower levels of sodium hydroxide than those required by the '894 patent.

72. To bring its existing AndroGel product within the claims of the '894 patent, Solvay filed a Request for a Certificate of Correction ("COC") with the PTO. In it, Solvay requested the insertion of a scientific term that would substantially reduce the amount of one of the components of the formulation and change the coverage of the claims. Despite this material change, Solvay falsely

represented to the PTO that this "correction" would not "alter the substance of the patent in any way that would necessitate reevaluation by an Examiner." Solvay further misrepresented that "the mistakes were made in good faith and that the proper language is contained throughout the specification," even though the desired language, a reference to "0.1N NaOH", appeared only once in the specification within Table 5.

73. The COC issued some six months later on December 16, 2003.

74. A COC applies only to causes of action that arise *after* the issuance of the COC. This rule reflects the policy that issuance of a patent serves a public notice function; patentees have a duty to carefully prepare their patent applications and then to police their patents when issued for accuracy and correctness.

75. Pursuant to 35 U.S.C. § 271(e)(2)(A), the filing of an ANDA constitutes an act of infringement. Thus, in this instance, the infringement claims that arose by operation of Watson and Paddock filing their ANDAs arose in May 2003, when the ANDAs were filed, prior to issuance of the COC. As a matter of law, the COC was inapplicable to Solvay's infringement litigation against Watson and Paddock. Solvay was precluded from invoking the "corrected" patent claims contained in the COC in those suits. As a result, because the claims of the '894 patent as issued did not apply to AndroGel or AB generic versions thereof, no

reasonable litigant could have believed that Watson's or Paddock's generic versions of AndroGel infringed the '894 patent.

76. In any event, as discussed below, even if the claims "corrected" by the COC were applicable in Solvay's suits against Watson and Paddock, no reasonable litigant could have believed that the "corrected" claims were valid.

D. Solvay's Improper Scheme to Obtain, List and, Assert the '894 Patent

77. Solvay was aware that the active drug substance in AndroGel (testosterone) was known and unpatentable. Solvay was also aware that, under Hatch-Waxman, its new dosage form exclusivity was set to expire on February 28, 2003 and that ANDAs seeking approval to market generic versions of AndroGel were likely to be filed immediately thereafter. Desperate to extend their monopoly, Solvay and Besins hatched a scheme to delay generic competition by obtaining a patent, listing that patent in the FDA's Orange Book under AndroGel's NDA (NDA No. 21-015), and delaying would-be generic competitors from entering the market for up to 30 months by suing them for patent infringement.

78. Timing was critical to the scheme. ANDA applicants need only file Paragraph IV certifications with respect to patents listed in the Orange Book. Without such a listing, Solvay and Besins could not file an infringement suit against would-be competitors to obtain the 30-month stay on FDA approval.

79. On January 7, 2003, less than two months before its exclusivity was to expire, Solvay obtained U.S. Patent No. 6,503,894 ("the '894 patent") and immediately had it listed in the Orange Book as applying to AndroGel.

80. In its fervor to expedite issuance of the '894 patent, Solvay botched its prosecution, obtaining a patent that did not apply to AndroGel or its likely generic equivalents. As a result, Solvay could not reasonably have believed that the '894 patent was properly listed in the Orange Book or infringed by the products that were the subject of Watson's and Paddock's ANDAs. In addition, many of the claims in the '894 patent were clearly invalid and could not reasonably be asserted against the ANDA filers for that reason. Furthermore, in its desperation to "correct" the fatal defects in its '894 patent, Solvay misrepresented facts regarding the '894 patent to the PTO.

81. At the time it submitted the '894 patent for listing in the Orange Book, Solvay could not reasonably have believed that the '894 patent was proper for listing. The FDA regulations in effect at the time provided that "[f]or patents that claim a drug substance or drug product, the applicant shall submit information only on those patents that claim a drug product that is the subject of a pending or approved application, or that claim a drug substance that is a component of such a product. For patents that claim a method of use, the applicant shall submit

information only on those patents that claim indications or other conditions of use of a pending or approved application." 21 C.F.R. § 314.53. The then-existing claims of the '894 patent did not support listing in the Orange Book because (a) the '894 patent did not claim AndroGel (or the testosterone drug substance that is a component of AndroGel) or (b) an approved method of use for AndroGel. Claims 1-30 of the '894 patent (as well as "corrected" versions of those claims) were also invalid because there was no written description support for the sodium hydroxide range stated therein. Solvay knew that its efforts to convince the Patent and Trademark Office ("PTO") to issue a patent prior to the expiration of AndroGel's dosage exclusivity had resulted in errors that prevented the '894 patent from applying to AndroGel or an approved method of using AndroGel.

82. It was well settled law that "[o]ne who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that [independent] claim." *Wahpeton Co., Inc. v. Frontier, Inc.*, 870 F.2d 1546, 1552 (Fed. Cir. 1989). As a result, unless AndroGel (or an approved method of using AndrGel) fell within the scope of one of the five originally issued independent claims (claims 1, 9, 10, 18 and 31) of the '894 patent, it could not fall within the scope of any of the remaining dependent claims in the '894 patent.

83. Prior to issuance of the COC, claims 1, 9, 10 and 18 required a formulation or composition having at least "about 1%" sodium hydroxide. As Solvay admitted in its pleadings from the patent litigation against Watson and Paddock, the phrase "sodium hydroxide" in the uncorrected '894 patent claims means the pure (anhydrous) form of sodium hydroxide. In addition, Solvay admits that the amount of sodium hydroxide recited in those claims is 50 to 250 times greater than the amount of sodium hydroxide in AndroGel. No reasonable litigant, therefore, could assert that claims 1, 9, 10 or 18, as they existed at the time the infringement suits were filed, covered either AndroGel, the testosterone drug substance that is a component of AndroGel, any generic version of AndroGel, or an approved method of use for AndroGel or any generic version thereof. To the contrary, Solvay admits that a skilled pharmaceutical chemist would recognize that the amount of pure (anhydrous) sodium hydroxide recited in originally-issued claims 1, 9, 10 and 18 "is far too caustic" and would do damage to the human skin. Thus, Solvay knew the independent claims 1, 9, 10 or 18, and their dependent counterparts, did not apply to AndroGel and the inclusion of the '894 patent in the Orange Book was unlawful.

84. The sole remaining independent claim, Claim 31, likewise could not reasonably be construed to cover a method for using AndroGel or a generic version

thereof. Claim 31 requires, among other things, a "pharmaceutical composition consisting essentially of: (i) about 0.5% to about 5% testosterone; (ii) about 0.1% to about 5% isopropyl myristate; (iii) about 30% to about 98% of an alcohol selected from the group consisting of ethanol and isopropanol; and (iv) about 0.1% to about 5% of a gelling agent . . . ." The phrase "consisting essentially of" indicates that a claim "necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). Thus, for a particular pharmaceutical composition to meet the limitations of claim 31, it (a) must include the listed ingredients in the required amounts and (b) must exclude any additional ingredient that materially affects the basic and novel properties of the invention. Solvay's own briefing admits that the basic and novel properties of the invention are the ability to produce plasma levels of testosterone sufficient to be effective in the treatment of hypogonadal patients. Sodium hydroxide materially affects the basic and novel properties of the purported invention, because the Carbopol gelling agent in the AndroGel formulation will not function properly (and will not produce plasma levels of testosterone sufficient to be effective in the treatment of hypogonadal patients) in the absence of sodium hydroxide. Under these circumstances, no reasonable

litigant could believe that claim 31 of the '894 patent encompassed a method for using AndroGel. Thus, neither claim 31, nor any claims depending on it, could have justified Solvay's submission of the '894 patent for listing in the Orange Book.

85. At the time Solvay filed patent infringement suits against Watson and Paddock, Solvay could not reasonably have believed that the manufacture, use or sale of the generic AndroGel products that were the subjects of the Generics' ANDAs would infringe the existing claims of the '894 patent. The proposed generic AndroGel products did not contain anywhere near the sodium hydroxide levels required by independent claims 1, 9, 10 and 18 of the '894 patent. As Solvay admitted, that amount of pure sodium hydroxide "is far too caustic" and would do damage to human skin. Thus, the Generics' ANDA products could not reasonably contain, and Solvay could not reasonably believe they contained, the amount of sodium hydroxide required by these claims. Solvay's lawsuits against the Generics were objectively baseless "shams" that no litigant could reasonably expect to win and were brought and maintained solely for the purpose of delaying generic competition against AndroGel.

86. Solvay's subjective recognition that it had no basis for asserting claims 1, 9, 10 and 18 (and their dependent claims) against the Generics is

reflected in its June 12, 2003 filing of a Request for Certificate of Correction. Thus, no later than June 12, 2003, Solvay knew its claims were defective and could not be asserted against Watson and Paddock. Likewise, Solvay knew of the defect in the sole remaining independent claim 31—namely, the combination of a narrow transition phrase ("consisting essentially of") and the absence of a limitation reciting sodium hydroxide (or another appropriate base), a critical component of the AndroGel formulation and the proposed generic versions of AndroGel. Despite Solvay's knowledge of these deficiencies, it nevertheless chose to file suit to trigger the 30 month regulatory stays.

87. Solvay's contention that the certificate of correction ("COC"), which did not issue for several months after Solvay filed suit, cured its impropriety, is frivolous. It is black letter law that a COC is "not effective" for "causes arising before its issuance." *Southwest Software, Inc. v. Harlequin, Inc.*, 226 F.3d 1280, 1294 (Fed. Cir. 2000). The Federal Circuit reaffirmed this well-settled statutory principle the week before the COC for the '894 patent issued. *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1353 (Fed. Cir. 2003) ("For causes of action that arise before the correction becomes effective, the patent must be considered without the benefit of the certificate of correction.") Thus, Solvay could not reasonably believe that its certificate of correction was effective for litigation

instituted in August 2003, which asserted a cause of action that arose upon the filing of the ANDAs in May 2003.

88. Nor could Solvay or any reasonable litigant have believed that Claims 1-30 were valid, either in their original or "corrected" form. Both sets of claims failed to comply with the written description requirement, and the "corrected" claims were invalid for the additional reason that Solvay was not entitled to the COC and had made misrepresentations to obtain it.

89. "The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not . . . ." *Amgen Inc. v. Hoescht Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003). To satisfy the written description requirement, the disclosure of the specification must "convey with reasonably clarity to those skilled in the art that, as of the filing date sought, [the inventor] was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Claims 1-30, both in their original and "corrected" form, recite a range of sodium hydroxide weight-to-weight percentages. Solvay's application for the '894 patent, as originally filed, teaches no range of sodium hydroxide for a pharmaceutical composition. Instead, the sole reference to sodium hydroxide was a single weight-to-weight percentage in a single example in Table 5. When Solvay later added the claimed ranges, it

accomplished the very thing the written description requirement forbids—namely, "later asserting that [it] invented that which [it] did not." *Amgen Inc.*, 314 F.3d at 1330. Nothing in Solvay's patent application could be viewed as conveying with reasonable clarity to those skilled in the art that, as of the filing of the application, the inventors were in possession of the ranges of sodium hydroxide later claimed, in either original or "corrected" form.

90. It was also unreasonable for Solvay to believe it was entitled to the COC. Section 255 of the patent law permits the Patent Office to correct mistakes of "minor character" or mistakes of a "clerical or typographical nature." 35 U.S.C. § 255. A mistake that, if corrected, would broaden a claim scope cannot be of a "minor character." A broadening correction can only be made when it is "manifest" or "immediately apparent" and where it is "clearly evident" from the intrinsic evidence that such a correction is the one appropriate was to correct the error.

91. The "error" asserted by Solvay did not satisfy these requirements. A reasonable litigant would have understood that the COC was invalid. Thus, even if the COC had been effective for the ANDA litigation (which it was not) it did nothing to bolster Solvay's baseless infringement claims. Furthermore, Solvay misrepresented the existence of written description support in its patent application

to obtain the COC. Solvay represented to the PTO that "the mistakes were made in good faith" and that "the proper language is contained throughout the specification, see for example, column 12, Table 5 ("0.1 N NaOH (sodium hydroxide))…As such, the correction does not involve such changes in the patent that would constitute new matter or that would require reexamination." These misrepresentations were knowingly made to obtain the COC. The reference to "0.1 N NaOH" appeared only once in (not "throughout") the specification. Solvay's requested change also introduced "new matter" because the specification did not disclose any ranges for "0.1 N NaOH" as recited by the "corrected" claims.

E. Generics Prepare to Challenge Solvay's Formulation Patent

92. In May 2003, Watson and Paddock each filed an application with the FDA for approval to market a generic version of AndroGel. As part of their ANDA applications, Watson and Paddock certified that their generic products did not infringe the '894 patent and that the patent was invalid.

93. Watson filed its ANDA before Paddock and was therefore eligible for 180-day exclusivity under the Hatch-Waxman Act.

94. With its ANDA, Paddock sought a partner to share the costs and risks associated with litigation, together with the rewards from a successful outcome. Paddock eventually reached a deal with Par Pharmaceuticals, Inc. ("Par"), which

was a top-ten generic drug company and a veteran of pharmaceutical patent litigation. Under the deal, Par agreed to share litigation costs with Paddock, market Paddock's generic-product following launch, and share in the resulting profits.

95. Watson notified Solvay on July 8, 2003 that it filed an ANDA containing a Paragraph IV certification that the '894 patent was invalid and/or not infringed. Paddock provided a similar Paragraph IV certification around that same time.

F. Solvay Files Sham Patent Infringement Actions Against Watson and Paddock

96. Following the ANDA filings, in August 2003, Solvay and Besins sued Watson and Paddock, alleging that each infringed the '894 patent by virtue of their ANDAs. They filed suit despite knowing that the '894 patent did not and could not apply to the generic AndroGel products proposed.

97. Before filing their complaints, Solvay's and Besins' only information relating to the Watson and Paddock products proposed in their ANDAs were the Paragraph IV notice letters, which detailed why the ANDAs and the proposed generic AndroGel products did not infringe the '894 patent. Prior to filing their complaints, Solvay and Besins did not request any sample of the Generics'

proposed products, any portion of their ANDAs, or any other information from Watson or Paddock relating to their proposed generic versions of AndroGel.

98. Under the Hatch-Waxman Act, Solvay's lawsuits triggered automatic stays of final FDA approval for the proposed generic versions of AndroGel until January 2006.

99. No reasonable litigant could have expected Solvay's patent infringement suits against Watson and Paddock to succeed, because (a) originally issued claims 1-30 of the '894 patent (as well as "corrected" versions of those claims) were invalid because there was no written description support for the sodium hydroxide range stated therein; (b) none of the issued claims could reasonably be interpreted as covering generic versions of AndroGel or a method of using generic AndroGel; (c) Watson and Paddock could not reasonably be viewed as infringing any of the "corrected" claims 1-30 of the '894 patent, because the certificate of correction was inapplicable to the litigation initiated before the certificate issued in December 2003 and because the certificate was invalid due to Solvay's misrepresentations to the PTO; and (d) claim 31 and its dependent claims could not reasonably be read to cover the use of Watson's or Paddock's AndroGel products, because Solvay purposefully excluded sodium hydroxide from claim 31. Solvay's knowledge that the generic versions of AndroGel at issue did not infringe

the '894 patent as issued is evidenced by the fact that Solvay sought a COC for the '894 patent *before* it filed its patent infringement suits.

100. Watson alleged in its answers and counterclaims to Solvay's sham infringement complaint that the '894 patent was invalid and asserted that Solvay was "improperly using [the litigation]," which was "meritless," for the wrongful and anticompetitive purpose of extending their monopoly on AndroGel by invoking the 30-month Hatch-Waxman stay and preventing the FDA from approving Watson's ANDA.

101. Watson and Paddock both filed counterclaims seeking a declaratory judgment that their products did not infringe the '894 patent and/or that the patent was invalid.

102. Recognizing the fatal flaws in the '894 patent, Watson and Paddock moved for summary judgment of invalidity as to certain claims in the patent. They would also have moved for summary judgment of non-infringement following the claim construction rulings by the Court if not for the settlement reached with Solvay

103. Both fact and expert discovery had concluded by July 2005, or thereabouts, over a year before the patent litigation was settled.

104. Summary judgment briefing between Solvay and Watson relating to invalidity was completed on January 19, 2006, approximately nine months before the patent litigation was settled, and the only summary judgment briefing that remained as of the date of settlement was the submission of Paddock's reply brief relating to invalidity.

105. As a result of the facts and circumstances detailed above, the Defendants knew (or should have known) that, because Solvay's patent claims were objectively baseless, absent settlement, Solvay would have lost the patent litigation on the merits.

G. Solvay Prepares for the Threat of Generic Competition

106. Paddock's ANDA was tentatively approved by the FDA on October 27, 2004. Paddock's ANDA received final approval on May 27, 2007.

107. In late January 2006, after the 30-month Hatch-Waxman stay expired, Watson's ANDA received final approval from the FDA, enabling Watson to market its AB-rated generic version of AndroGel. Watson was awarded 180 days of market exclusivity for being the first to file an ANDA for generic AndroGel containing a Paragraph IV certification.

108. With final FDA approval, Watson could launch its generic version of AndroGel on January 27, 2006, unless Solvay was able to obtain a preliminary

injunction in the patent case to prevent Watson's launch. Solvay knew that Watson's receipt of final FDA approval in January 2006 meant generic competition was imminent for its AndroGel franchise. Prior to January 2006, Solvay had little incentive to settle the sham litigation; the 30-month Hatch-Waxman stay was in effect, which protected AndroGel from generic competition. However, after the expiration of the stay and FDA approval of Watson's ANDA, Watson was now free to launch its generic version of AndroGel.

109. Solvay recognized that additional generic competition would arise from approval of Paddock's ANDA. The CEO of Paddock's partner Par told investment analysts in February 2006 that if generic AndroGel didn't launch in 2006, it "should certainly hit in 2007."

110. Despite the imminent threat of generic competition, Solvay did not seek court intervention to enjoin Watson's or Par/Paddock's launch, an effort Solvay knew would be unsuccessful. Instead, Solvay took action to (a) settle its patent litigations that had successfully delayed generic competition thus far, and (b) eliminate the threat of generic competition going forward without risking a potential adverse court decision.

111. In preparation for settlement negotiations with Watson and Paddock/Par, Solvay put together a financial model to analyze its settlement

options, known internally as "Project Tulip." Solvay determined that it wanted to defer generic entry until 2015. The purpose of "Project Tulip" was to assess whether the Generics would accept this delayed entry date by evaluating the Generics' expected return from continuing to litigate. From this analysis, Solvay concluded that Watson and Paddock/Par might agree to a settlement that delayed generic entry. However, if Solvay wanted a settlement that delayed generic entry until 2015, it determined it would have to pay the Generics for that delay. Solvay's analysis indicated it could easily afford to buy the Generics' agreement not to compete, eliminating the near-term threat of generic entry. By delaying competition and maintaining supracompetitive pricing, Solvay and the Generics would preserve monopoly profits, which could then be shared among themselves at the expense of the consumer savings that would have resulted from price competition. Even after paying a share of monopoly profits to the Generics to secure their agreement not to compete, Solvay still expected to make more in AndroGel profits by delaying generic entry until 2015 than by continuing to litigate (and eventually lose) the sham patent lawsuits.

H. Solvay and Watson Enter into Agreement Not to Compete

112. Solvay initiated discussions concerning a settlement of the litigation with Watson. The premise of the discussion was that Watson would be paid by Solvay as consideration for not launching its generic product.

113. At the beginning of settlement negotiations, Watson proposed that Solvay share AndroGel revenues with Watson through an arrangement under which Watson would "co-promote" AndroGel to doctors. Just months before, a consulting firm hired by Solvay conducted a comprehensive analysis of Solvay's AndroGel promotion efforts. That analysis concluded that AndroGel co-promotion was unlikely for Solvay, and in any event, Watson did not meet the set of criteria for potential co-promotion partners. Yet because Solvay wanted to protect its monopoly AndroGel revenues until 2015, Solvay quickly agreed to consider allocating a portion of AndroGel sales to Watson.

114. Watson was willing to accept Solvay's 2015 generic entry date only if it was compensated for that delay under the pre-textual "co-promotion" arrangement.

115. The amount of Solvay's payment to Watson also had to be substantial enough to compensate Watson for the risk posed by a planned new version of AndroGel, to be marketed by Solvay that threatened to destroy the market for

AndroGel and make Watson's generic AndroGel product far less valuable. Branded pharmaceutical companies frequently introduce a "line extension," or a new branded product that is related to but different from an existing product, to preserve sales of a branded franchise. In the case of AndroGel, Solvay plans to develop and market a testosterone gel containing 1.62% testosterone—more than the 1% testosterone contained in AndroGel—that would allow patients to achieve similar therapeutic benefits with less gel. Solvay plans to shift sales from AndroGel to its new product before 2015, in part because generic versions of AndroGel will not be automatically substitutable for Solvay's new branded product.

116. During settlement negotiations, Solvay informed Watson of its plans for its line extension product. Watson accepted Solvay's 2015 generic entry date even though a line extension product could have a severe negative impact on its potential sales of generic AndroGel by 2015. Watson would not have accepted the 2015 generic entry date in light of these risks, absent Solvay's substantial sharing of AndroGel profits through the co-promotion deal.

117. On September 13, 2006, Solvay and Watson entered written agreements to settle their patent litigation. Under the parties' settlement, Watson agreed to refrain from marketing generic AndroGel until August 31, 2015, or

earlier if another generic company launched a generic version of AndroGel before that date. Watson's 180-day exclusivity period meant that Watson effectively could block later generic entrants by delaying its own market entry.

118. Solvay and Watson simultaneously entered into a co-promotion deal that provided substantial compensation to Watson. Under the deal, Watson agreed to promote AndroGel to urologists, and Solvay agreed to share AndroGel profits with Watson. At the time it negotiated the deal, Solvay projected it would pay Watson approximately $19 million during the first year of the agreement, with that amount rising to over $30 million annually by the end of the deal.

119. Under the co-promotion agreement, Watson can also co-promote any line extension of AndroGel including the new 1.62% AndroGel product.

120. Solvay's compensation of Watson was designed to, and did, induce Watson to settle the AndroGel patent litigation and agree to refrain from marketing generic AndroGel until 2015. Rather than compete, Solvay and Watson agreed to share in AndroGel monopoly profits. Solvay and Watson both determined that they would be better off cooperating and sharing in Solvay's monopoly profits than by competing.

121. Solvay and Watson filed a voluntary stipulation of dismissal terminating their patent litigation in the district court. The parties did not file their

settlement and co-promotion agreements with the court; nor were the agreements contingent on court approval.

I. Solvay, Par and Paddock Agree Not to Compete

122. Under its partnership with Paddock, Par was responsible for conducting the patent litigation with Solvay and negotiating any settlement.

123. Par, like Watson, was willing to settle the AndroGel patent litigation with Solvay, and delay its entry to 2015, only if it received compensation for that delay. During negotiations, Par quickly accepted Solvay's proposed 2016 generic entry date, contingent on the parties' ability to reach agreement on the value Par would receive in a settlement. That compensation was accomplished by means of a pretextual "co-promotion" agreement. In the words of a senior Par executive, Par was looking to "extract payments" from Solvay in settlement negotiations.

124. To agree on a value, Solvay and Par exchanged forecasts analyzing the profits Par would make from sales of generic AndroGel beginning in 2007. These forecasts discounted Par's generic AndroGel revenues to reflect Par's probability of prevailing in the patent litigation. According to a senior Solvay executive, Solvay developed these forecasts to "demonstrate to [Par] what [its] options are, either to litigate or enter into these—this business arrangement . . .and

if we entered into the business arrangement, we wouldn't be litigating. They go hand in hand."

125. Based on this financial analysis, Solvay and Par were able to "agree on a value" that Par would receive in exchange for settling the litigation. Solvay and Par agreed on the payments Par would receive *before* agreeing on what Par would do in exchange, other than defer generic entry until 2015. On May 13, 2006, Solvay and Par/Paddock confirmed via email their "agreed upon settlement of $12 million per year for 6 years coupled with manufacturing/ development and/or a co-promotion between Par and Solvay."

126. After the parties agreed on the amount that Solvay would pay Par, the parties met to discuss what type of business arrangement would accompany the settlement and how they would allocate the agreed-upon payments. The parties decided that Par would co-promote AndroGel to doctors and receive $10 million annually, while Paddock would serve as a back-up manufacturer for AndroGel and receive $2 million annually. As a Besins executive stated in an e-mail, a "backup manufacturer strategy [was] a partial way to compensate Parr [sic] for not entering the market."

127. On September 13, 2006, the same day the Solvay/Watson agreements were signed, Solvay, Besins, Par, and Paddock entered written agreements to settle

their patent litigation. Under the parties' settlement, Par and Paddock agreed to refrain from marketing generic AndroGel until February 28, 2016, or earlier if another generic company, including Watson, launched a generic version of AndroGel before that date.

128. At the same time Par signed its agreements with Solvay, it agreed to transfer $6 million upfront to Paddock through a transfer of title of Paddock's ANDA to Par. This payment was necessary to obtain Paddock's assent to the settlement.

129. The compensation Solvay agreed to provide Par and Paddock was designed to, and did, induce Par and Paddock to settle the AndroGel patent litigation by agreeing to refrain from marketing generic AndroGel until 2016. Rather than compete, Solvay, Par and Paddock agreed to cooperate on AndroGel and share in monopoly profits.

130. The district court hearing the patent litigation dismissed Solvay's patent lawsuit against Paddock under a consent judgment filed by the parties. As part of their agreement, and in order to secure payments from Solvay, Paddock acknowledged that the '894 patent was valid and enforceable. The parties did not file their settlement, co-promotion, and back-up manufacturing agreements with the court; nor were the agreements contingent upon court approval.

131. Upon information and belief, both Watson and Par notified the FDA in 2009 that they were withdrawing their ANDA's for generic AndroGel and, as a result, neither Generic Defendant will be in a position to enter the market with a generic product in 2015 or in the foreseeable future, ensuring that Solvay will continue to maintain a monopoly over AndroGel, charging supracompetitive prices, indefinitely.

J. Solvay Paid Watson and Par/Paddock Through "Business Deals" That Made Sense Only When Linked to Deferred Generic Entry

132. In total, Solvay paid millions of dollars to Watson, Par, and Paddock to compensate each for agreeing to delay market entry.

133. Perhaps mindful that "exclusion payments" are *per se* illegal, Defendants touted the payments in their agreements as fees for "co-promotion" and "back-up manufacturing." These rationales were pretextual and meant to obscure the fact that Solvay and the Generics had agreed to horizontally allocate the market for AndroGel. The payment of these "fees" was Defendants' mechanism for transferring from Solvay to the Generics some of the monopoly profits that would be earned by Solvay during the period when generic entry was foreclosed. The co-promotion, back-up manufacturing, and other pretextural rationales for the payments were of little or no real value to Solvay and in any event were worth far

less than the millions of dollars Solvay paid to the Generics pursuant to the agreements.

134. Solvay's co-promotion deals with Watson and Par are not independent business transactions for at least the following reasons:

a. Prior to settlement discussions with Watson and Par, Solvay was not looking for co-promotion. Its 2006 business plan for AndroGel assumed "no co-promotion during the plan period," two prior AndroGel co-promotion efforts had been cancelled because they had "no significant impact" on sales trends, and a late 2005 analysis from a consulting firm concluded that future AndroGel co-promotion offered "little revenue upside."

b. Solvay's payments to Watson and Par far exceeded the value of any services provided.

c. Other terms of the co-promotion deals depart from industry standards. For example, unlike Solvay's previous AndroGel co-promotion agreements, Solvay cannot terminate the deal early if co-promotion does not improve AndroGel sales.

d. Before agreeing to the co-promotion deals, Solvay did not analyze how the Watson or Par co-promotion efforts would affect AndroGel sales, as it did before entering into earlier co-promotion agreements. Solvay instead examined the "Estimated Impact of Settlement" on Solvay's budget and accounted for co-promotion as a cost of settlement rather than a profitable business deal.

135. Solvay's back-up manufacturing deal with Paddock is not an independent business transaction for at least the following reasons:

a. The back-up manufacturing deal guarantees Paddock $2 million per year for six years, regardless of whether Paddock ever manufactures AndroGel or ever becomes FDA-qualified to manufacture AndroGel.

b. Before entering into the back-up manufacturing deal, Solvay conducted no diligence on Paddock's manufacturing facilities. Solvay has paid Paddock $2 million per year since September 2006 despite the fact that Solvay did not even apply for the required FDA approval for Paddock to serve as back-up manufacturer until November 2008.

136. The agreements between Solvay and the Generics were and are anticompetitive and foreclosed the possibility of competition in the AndroGel market in exchange for payments to potential competitors.

137. Perrigo Company purchased all or part of the assets of Paddock in 2011. Upon completion of the asset purchase, Perrigo joined the ongoing unlawful course of conduct -- and joined the unlawful agreements, collusion and conspiracy -- with respect to the suppression of generic competition for AndroGel. Perrigo did not withdraw from that conspiracy, but instead participated in it.

138. In 2012, Abbott, parent of Solvay, announced its plan to spin off most of its prescription drug business to a new entity, AbbVie. That plan came to fruition as of January 1, 2013. As successor to Abbott (Solvay), AbbVie has stepped into the shoes of Solvay with respect to the unlawful agreements with the Generic Defendants. AbbVie has continued to comply with Solvay's obligations under the unlawful agreements and the Generic Defendants have not entered the market with generic AndroGel.

139. Upon transition of the AndroGel business from Solvay to AbbVie in January, 2013, AbbVie joined the on-going conspiracy with respect to the suppression of competition in the market for generic AndroGel. AbbVie did not withdraw from the conspiracy, but instead participated in it.

140. Had the Defendants settled the patent lawsuits in a pro-competitive manner, the Generic Defendants would have been allowed to enter the AndroGel market, earlier than under the agreements at issue, thus saving Plaintiffs and members of the Class millions of dollars.

K. The Unlawful Agreements to Suppress Generic Competition for AndroGel are On-Going and Continue to Cause Injury.

141. To this day, no generic AndroGel is available in the United States market. AbbVie continues to sell AndroGel at inflated prices and Plaintiffs have been denied the lower prices that generic competition would have permitted on the market. The lack of generic competition is a direct, and on-going, result of the unlawful agreements among the Defendants. Given the success of Defendants' anticompetitive scheme, the lack of generic competition for AngroGel is ongoing and may continue indefinitely now that the Generic Defendants have withdrawn their ANDAs for the right to sell a generic version of AndroGel.

142. Since the unlawful agreements were made, Defendants' unlawful conduct in violation of the antitrust laws has been on-going, payments have been

made from Solvay and AbbVie to the Generic Defendants to compensate them for refraining from entering the market, and Plaintiffs have been and continue to be injured with each purchase of AndroGel each day that the unlawful agreements have been in effect.

L. Solvay's Patent Was Unlikely to Prevent Generic Competition for AndroGel

143. Before Solvay paid Watson and Par/Paddock for their agreements not to market their respective generic versions of AndroGel, the Generics amassed substantial evidence that their generic products did not infringe the formulation patent and argued that the patent was invalid and/or unenforceable.

144. Watson and Par/Paddock argued that the scope of the formulation patent was limited and that their products were outside the scope of the patent claims. They argued that their generic products did not infringe the patent, because their products contained ingredients that the patent did not cover, or amounts of ingredients outside the amounts covered by the patent.

145. Watson and Par/Paddock also argued that the formulation patent was invalid. Among other things, these firms developed substantial evidence that:

- The patent was invalid under 35 U.S.C. § 102(b) for prior commercial sale or public use of patented invention, in that Besins offered the invention for sale to Solvay in 1995—a fact that Solvay and Besins withheld from the Patent and Trademark Office.

- The patent was invalid as obvious under 35 U.S.C. § 103, because the gel formulations and related methods covered by the patent were obvious variations of existing products and methods.

- Many of the patent claims were invalid under 35 U.S.C. § 112 for failure to meet the "written description" requirement.

146. Watson argued that the patent was unenforceable, because Solvay and Besins did not disclose their 1995 commercial supply agreement to the patent examiner when they applied for the '894 formulation patent. The Generics also argued that the certificate of correction that changed the scope of some of the patent claims was invalid and/or did not apply to the pending litigation, which was filed before the certificate of correction issued.

147. By late 2005, Watson and Par/Paddock had filed motions for summary judgment on two of these issues and addressed others in claim construction briefing and expert reports.

148. Solvay bore the burden of proving that Watson and Par/Paddock each infringed the formulation patent—in other words, that the generic products were within the scope of the patent claims. Solvay had not met their burden when the litigation ended in settlements.

149. Solvay was unlikely to prevent generic entry through its patent lawsuits. To do so, Solvay had to prove infringement by both Watson and

Par/Paddock and also had to defeat each of the Generics' invalidity and unenforceability arguments. If either Watson or Par/Paddock prevailed on any one of these issues, Solvay's formulation patent would not have prevented generic entry.

150. Recognizing the weakness of its patent claims, Solvay entered into agreements to pay the Generics millions of dollars to refrain from entering the market, rather than seeking injunctive relief or receiving a final judgment on its sham patent claims from the Court.

VI. INTERSTATE AND INTRASTATE COMMERCE

151. Defendants' efforts to restrain competition in the market for AndroGel and its generic equivalents have substantially affected interstate and intrastate commerce.

152. At all material times, Defendant Solvay manufactured, promoted, distributed, and sold substantial amounts of AndroGel in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

153. At all material times, Defendant Solvay transmitted funds as well as contracts, invoices, and other forms of business communications and transactions

in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of AndroGel.

154. In furtherance of their efforts to and restrain competition in the market for AndroGel and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Defendants were within the flow of and have substantially affected interstate commerce.

155. Defendants' anticompetitive conduct had substantial intrastate effects in every state of purchase in that, among other things, retailers within each state were foreclosed from offering cheaper generic equivalents of AndroGel to purchasers within each state, which directly impacted and disrupted commerce for consumers and third-party payors within each state.

VII. RELEVANT MARKET AND MARKET EFFECTS

156. To the extent it is necessary to define a relevant product market, the relevant product market is AndroGel and its generic bioequivalents rated "AB" by the FDA. AndroGel would not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of AndroGel. The relevant geographic market is the United States. Solvay's market share in the relevant product and geographic markets is 100%.

157. At all relevant times, Defendant Solvay had market power over the market for AndroGel because it had the power to maintain the price of AndroGel at supracompetitive levels without losing substantial sales. Defendant Solvay needed to control only AndroGel and its AB-rated generic equivalents, and no other products, in order to maintain the price of AndroGel profitably at supracompetitive levels. Only the market entry of a competing, AB-rated generic version of AndroGel would render Defendant Solvay unable to profitably maintain their current prices of AndroGel without losing substantial sales.

158. Defendant Solvay sold AndroGel at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins. Defendant Solvay, at all relevant times, enjoyed high barriers to entry with respect to AndroGel.

159. Prior to Solvay's filing of the sham patent suits, Watson and Paddock had filed ANDAs to market an AB-rated generic equivalent to AndroGel. But for the filing and maintenance of the sham litigation and the anticompetitive settlement agreements through which Defendants agreed not to compete Paddock and Watson would have begun selling generic AndroGel well in advance of 2015 and well before Solvay could convert substantial sales of AndroGel to their new product, AndroGel 1.62%.

160. Prior to settlement of the sham lawsuits and execution of agreements between Solvay and the Generics, Solvay and Watson were potential competitors. By entering into their agreements, Solvay and Watson eliminated the potential that (a) Watson would have marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (b) Watson would have prevailed in the patent litigation and marketed generic AndroGel before 2015; or (c) Solvay and Watson would have agreed to settle their patent litigation on terms that did not compensate Watson for abstaining from selling AB-rated generic AndroGel, but would have provided for generic entry earlier than 2015.

161. Prior to settlement, Solvay and Par/Paddock were potential competitors. By entering into the agreement, Solvay and Par/Paddock eliminated the potential that (a) Par/Paddock would have marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (b) Par/Paddock would have prevailed in the patent litigation and marketed generic AndroGel well before 2015; or (c) Solvay and Par/Paddock would have agreed to settle their patent litigation on terms that did not compensate Par/Paddock for abstaining from selling AB-rated generic AndroGel, but would have provided for generic entry earlier than 2015.

162. Defendants eliminated this potential competition by entering agreements that compensated Watson and Par/Paddock for refraining from marketing generic AndroGel until 2015. These agreements, which eliminated potential competition until 2015, were based not on the strength of Solvay's patent, but on the compensation Solvay provided to Watson, Par, and Paddock in exchange for a delayed generic entry date. Absent compensation, Watson and Par/Paddock would not have agreed to refrain from competing until 2015, the generic entry date that Solvay demanded.

163. Moreover, absent the compensation Solvay agreed to provide, generic competition to AndroGel would have occurred before 2015 because (a) Watson and/or Par/ Paddock would have marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (b) Solvay would not have prevailed against each of Watson and Par/Paddock in the patent litigations; or (c) Solvay would have agreed to settle the patent litigation on terms that did not compensate Watson and Par/Paddock for abstaining from selling AB-rated generic AndroGel, but would have provided for generic entry earlier than 2015.

164. Entry of generic AndroGel would result in a fundamental shift in the market from Solvay's branded AndroGel to lower-priced AB-rated generic versions of AndroGel. Through their anticompetitive conduct, Defendants have

(a) delayed generic entry and (b) retained those potential purchaser savings for themselves.

165. Through the overarching anticompetitive scheme, including the exclusion payment agreements, Defendants knowingly and intentionally conspired to maintain and enhance Solvay's monopoly power in the relevant market by blocking and delaying market entry of AndroGel. The unlawful exclusion payment agreements between Defendants allocated 100% of the AndroGel and its generic bioequivalent rated "AB" market in the United States; delayed the sales of generic AndroGel products for as long as nine years or more; and fixed the price at which consumers and other End-Payor Plaintiffs would pay for AndroGel at the higher, branded price.

166. The goal, purpose and/or effect of the agreements was to maintain and extend Solvay's monopoly power in the United States market for AndroGel and its generic bioequivalents rated "AB". The exclusion payment agreements prevented and/or delayed generic competition to AndroGel and enabled Solvay to continue charging supracompetitive prices for AndroGel without a loss of sales sufficient to make those prices unprofitable.

167. Defendants specifically intended that the exclusion payment agreements would maintain Solvay's monopoly power in the relevant market, and injured Plaintiffs and the Class thereby.

168. Defendants each committed at least one overt act in furtherance of the conspiracy.

169. As a direct and proximate result of Defendants' unlawful restraint of trade and unlawful maintenance and conspiracy to maintain Solvay's monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for AndroGel, as described herein, and were harmed as a result.

170. The Hatch-Waxman Act was designed to promote generic competition while preserving incentives for branded innovation. The filing of sham litigation and/or the use of exclusion payments to prevent generic competition, such as Defendants have done, distorts the careful balance achieved by the Hatch-Waxman Act by eliminating generic companies' incentives to compete.

171. Exclusion payments are not a natural by-product of incentives created by the Hatch-Waxman Act. Rather, pharmaceutical patent litigation can be, and often is, resolved without exclusion payments from branded companies to generic companies.

172. Through its improper Orange Book listing, sham litigations, and exclusion payment settlements, Solvay bought protection from competition not contemplated by the Hatch-Waxman Act—with purchasers paying the price for its anticompetitive conduct.

VIII. CLASS IMPACT

173. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of AndroGel. As a result of Defendants' illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for AndroGel. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because (a) the price of brand-name AndroGel was artificially inflated by Defendants' illegal conduct and/or (b) Class members were deprived of the opportunity to purchase lower-priced generic versions of AndroGel sooner.

174. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

IX. CLASS ACTION ALLEGATIONS

175. Plaintiffs bring their claims on behalf of themselves and all End-Payor purchasers of AndroGel, *i.e.* consumers and third-party payors, the last persons and entities in the chain of distribution, who purchased AndroGel, for purposes other than for resale.

176. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a) and (b)(3), as representatives of one or all of the End-Payor Purchaser Classes defined below:

> All Third Party Payors in the United States who purchased and/or paid for some or all of the purchase price for AndroGel and/or its AB-rated generic equivalents and all individuals who paid all or a portion of an AndroGel prescription in California, excluding those whose payments were solely fixed tier co-payments.
>
> Third Party Payors ("TPPs") are health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare plans, and other health benefit providers and entities with self-funded plans that contract with a health insurer or administrator to administer their prescription drug benefits. These payors include such private entities that may provide prescription drug benefits for public benefits programs, but only to the extent that such private entity was at risk for the cost of the payment(s). These payors also include all such entities that may provide prescription drug benefits for current or former public employees, but only to the extent that such entity was at risk for the cost of the payment(s).
>
> An entity "purchased" or "paid for" AndroGel if it paid some or all of the purchase price, or reimbursed any part of the purchase price paid by its members, employees, insureds, participants or beneficiaries.

Individuals with a "fixed tier co-payment" are those individuals whose purchases of AndroGel were made pursuant to contracts with TPPs whereby the amount of the co-pay obligation does not differ between a branded and generic bioequivalent AndroGel product.

177. The following persons or entities are also excluded from the proposed End-Payor Class:

a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;

b. All governmental entities, except for governmental funded employee benefit plans;

c. All persons or entities who purchased AndroGel or its AB-rated generic equivalent for purposes of resale or directly from Defendants or their affiliates;

d. Fully insured health plans (i.e., Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);

e. The judges in this case and any members of their immediate families.

178. Except for transactions, if any, that are subject to capitation agreements, Pharmacy Benefit Managers (entities that transmit payments to pharmacies as part of the administrative services they perform for third party payors) do not fit the definitions of the Class and are not Class members.

179. Plaintiffs believe, and therefore aver, that there are thousands of members in the above Classes; their exact number and identities being unknown to

the Plaintiffs, but known to Defendants and/or ascertainable through appropriate discovery.

180. Plaintiffs' claims are typical of the claims of the members of each Class because Plaintiffs and all members of the End-Payor Purchaser Classes were injured in the same manner by Defendants' unlawful, anticompetitive, and inequitable methods, acts, and practices, and wrongful conduct complained of herein, i.e., Plaintiffs and all members of the Classes have paid supracompetitive and artificially high prices for AndroGel.

181. Plaintiffs will fairly and adequately protect and represent the interests of all members of each Class. The interests of the Plaintiffs are coincident with, and not antagonistic to, those of each Class.

182. Plaintiffs have retained counsel experienced in the prosecution of class action antitrust litigation, and who have particular experience with class action antitrust litigation involving pharmaceutical products.

183. Questions of law and fact common to the members of each Class predominate over any questions that may affect only individual Class members.

184. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Each Class is readily definable, and prosecution as a class action will eliminate the possibility of duplicative litigation

while also providing redress for claims that would otherwise be too small to support the expense of individual, complex litigation.

185. Among the questions of law and fact common to the Classes are:

a) whether Defendants have unlawfully monopolized or attempted to monopolize the market for AndroGel in the United States;

b) whether Defendants unlawfully extended their monopoly power over the market for AndroGel;

c) whether Defendants conspired to monopolize the market for AndroGel and its AB-rated generic equivalents

d) whether Defendants conspired to suppress generic competiton for AndroGel;

e) whether Defendants entered into unlawful agreements in restraint of trade;

f) whether Solvay's payments to Generic Defendants were for a purpose other than delayed entry of AndroGel;

g) whether, pursuant to the exclusion payment agreements, Solvay paid the Generic Defendants;

h) whether Solvay's payments to the Generic Defendants were necessary to yield some pro-competitive benefit that is cognizable and non-pretextural;

i) whether Solvay's introduction of AndroGel 1.62% was intended to impede generic competition;

j) whether one or more of the Exclusion Payment Agreements is illegal under a rule of reason;

k) whether Defendants, through their conduct, have caused the prices of AndroGel to be maintained at supracompetitive levels;

l) whether, and to what extent, Defendants' conduct caused antitrust or other injury (*i.e.*, overcharges) to Plaintiffs and the members of the Class; and

m) whether Defendants were unjustly enriched to the detriment of the Unjust Enrichment Class, entitling Plaintiffs and the Unjust Enrichment Class to disgorgement of all monies resulting therefrom.

186. Defendants have acted or refused to act, as alleged herein, on grounds generally applicable to each Class, thereby making appropriate final injunctive relief and/or corresponding declaratory relief with respect to the Classes as a whole.

X. FRAUDULENT CONCEALMENT TOLLED ALL APPLIABLE STATUTES OF LIMITATIONS

187. Plaintiffs and members of the Class had no detailed knowledge of Defendants' unlawful self-concealing agreements and could not have discovered the conspiracy through the exercise of reasonable diligence during the applicable limitations periods.

188. This is so both because of the nature of Defendants' conspiracy was self-concealing and because Defendants employed techniques of secrecy to avoid detection of, and to fraudulently conceal, their contract, combination, conspiracy, and conduct. Defendants wrongfully and affirmatively concealed the existence of

their continuing combination and conspiracy from Plaintiffs by, among other things:

a) Concealing the amounts that Solvay was to pay, and did pay, to each of Watson, Par, and Paddock under the Exclusionary Payment Agreements and that those payments far exceeded any lawful economic benefit Solvay received from the Generic Defendants under the agreements;

b) Issuing various press releases concerning the settlement of the '894 patent litigation indicating that payments from Solvay to Watson, Par and Paddock under the Exclusionary Payment Agreements were compensation for the co-promotion of AndroGel or for back-up manufacturing services when in fact Solvay was paying Watson, Par and Paddock not to launch their AB-rated generic version of AndroGel.

c) In its press release, Watson claimed that the Agreements would permit Watson to launch a generic equivalent to AndroGel in 2015, "five years earlier than the last-to-expire patent – a win for both patients and Watson." Watson failed to disclose that the agreement

substantially delayed generic entry by Watson, compared to when it would have occurred absent the unlawful payments.

d) Watson also failed to disclose that a generic version of AndroGel would be delayed long enough for Solvay to convert sales of AndroGel to AndroGel 1.62% or that under the agreements Watson would continue to enjoy payment from Solvay resulting from Watson's co-promotion of AndroGel 1.62%.

e) In its press release Par claimed the agreements would allow Par to sell its generic Androgel no later than February 26, 2016, "more than four years prior to the expiration of the ['894 Patent]." Par failed to disclose that the agreements substantially delayed introduction of generic entry by Par, compared to when it would have occurred absent the unlawful payments.

f) In its press release Par indicated that it agreed "that the ['894] patent is valid and enforceable and that Par infringes the patent." Par failed to divulge that its representations about the validity of the '894 patent were solely the result of the payments received from Solvay under the agreements and did not reflect a legal analysis of the strength of the '894 patent.

189. Because the conspiracy was both self-concealing and affirmatively concealed by Defendants, Plaintiffs and members of the Class had no knowledge of the conspiracy or of any facts or information that would have caused a reasonably diligent person to investigate whether an illegal combination or conspiracy existed.

190. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting the Plaintiffs' and the Class's claims have been tolled.

XI. CONTINUING VIOLATION

191. This Consolidated Amended Complaint alleges a continuing course of conduct (including conduct within the limitations periods), and Defendants' unlawful conduct has inflicted continuing and accumulating harm within the applicable statutes of limitations. Thus, Plaintiffs and the members of the Class can recover for damages that they suffered during any applicable limitations period.

XII. CLAIMS FOR RELIEF

CLAIM I: MONOPOLIZATION UNDER STATE LAW (Asserted against Solvay)

192. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

193. This claim is pled as to Solvay.

194. At all relevant times, Solvay possessed substantial market power (i.e., monopoly power) in the relevant market. Solvay possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

195. Through the overarching anticompetitive scheme, as alleged above, Solvay willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs and the Class thereby.

196. It was Solvay's conscious objective to further its dominance in the relevant market by and through the overarching competitive scheme.

197. Solvay's scheme harmed competition as aforesaid.

198. As a direct and proximate result of Solvay's illegal and monopolistic conduct, as alleged herein, Plaintiffs and the Class were harmed as aforesaid.

199. By engaging in the foregoing conduct, Solvay has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases in California by members of the Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

e. Iowa Code § 553.5 *et seq.*, with respect to purchases in Iowa by members of the Class.

f. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class.

g. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases in Maine by members of the Class.

h. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases in Michigan by members of the Class.

i. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

j. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Class.

k. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by members of the Class.

l. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class.

m. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by members of the Class.

n. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

o. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases in North Dakota by members of the Class.

p. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class.

q. 10 L.P.R.A. § 260, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

r. R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases in Rhode Island by members of the Class.

s. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by members of the Class.

t. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases in Utah by members of the Class.

u. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

v. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by members of the Class.

w. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

CLAIM II: CONSPIRACY TO MONOPOLIZE UNDER STATE LAW
(Asserted against all Defendants)

200. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

201. This claim is pled as to all Defendnats.

202. With regard to all conduct complained of above, at all relevant times, Solvay acted in concert with Generic Defendants to maintain Solvay's monopoly power.

203. At all relevant times, Solvay possessed substantial market power (i.e., monopoly power) in the relevant market. Solvay possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

204. Through the anticompetitive scheme alleged herein Solvay and Generic Defendants conspired to maintain Solvay's monopoly power in the relevant market in order to block and delay market entry of AndroGel, i.e., AB-rated generic versions of AndroGel. The scheme allocated all sales of AndroGel in the United States to Solvay and Generic Defendants; delayed the sales of generic AndroGel; and fixed the price at which Plaintiffs and members of the Class would pay for AndroGel at the higher, branded price.

205. The goal, purpose and/or effect of the scheme was to maintain and extend Solvay's monopoly power in the United States market for AndroGel. The scheme prevented and/or delayed generic competition to AndroGel and enabled

Solvay to continue charging supracompetitive prices for AndroGel without a substantial loss of sales.

206. Solvay and Generic Defendants knowingly and intentionally conspired to maintain and enhance Solvay's monopoly power in the relevant market. In turn, Solvay agreed to share with the Generic Defendants the monopoly profits from the sale of branded AndroGel.

207. Solvay and Generic Defendants specifically intended that their scheme would maintain Solvay's monopoly power in the relevant market, and injured Plaintiffs and the Class thereby.

208. Solvay and Generic Defendants each committed at least one overt act in furtherance of the conspiracy.

209. There is and was no legitimate, nonpretextual procompetitive justification for Solvay and Generic Defenants' actions comprising the anticompetitive scheme that outweighs their harmful effect. Even if there were some conceivable such justification, the scheme is and was broader than necessary to achieve such a purpose.

210. As a direct and proximate result of Solvay and Generic Defendants' concerted conduct, as alleged herein, Plaintiffs and the Class were harmed as aforesaid.

211. By engaging in the foregoing conduct, Solvay and Generic Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class.

a. D.C. Code Ann. §§ 28-4503, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

b. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

c. Iowa Code § 553.3 *et seq.*, with respect to purchases of Lidoderm and AB-rated generic equivalents in Iowa by members of the Class.

d. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Class.

e. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class.

f. Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases in Maine by members of the Class.

g. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Class.

h. Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases in Minnesota by members of the Class.

i. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Class.

j. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by members of the Class.

k. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class.

l. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by members of the Class.

m. New York General Business Law § 340, *et seq.*, with respect to purchases in New York by members of the Class.

n. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

o. N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases in North Dakota by members of the Class.

p. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class.

q. 10 L.P.R.A. § 251, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

r. R.I. Gen. Laws §§ 6-36-7 *et seq.*, with respect to purchases in Rhode Island by members of the Class.

s. S.D. Codified Laws Ann. § 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by members of the Class.

t. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases in Utah by members of the Class.

u. Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

v. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by members of the Class.

w. Wis. Stat. § 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class

CLAIM III: CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW
(Asserted against All Defendants)

212. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

213. This claim is pled as to all Defendants.

214. In or about September 2006 and at times prior to the formal execution thereof Defendants entered into the Agreements, a continuing illegal contract, combination and conspiracy in restraint of trade under which Solvay agreed to pay Watson and Par/Paddock substantial consideration in exchange for Generic Defendants' agreement to delay bringing their generic version of AndroGel to the market, the purpose and effect of which were to: (a) allocate 100% of the market for AndroGel in the United States to Solvay; (b) prevent the sale of generic versions of AndroGel in the United States, thereby protecting AndroGel from any generic competition for over nine years; (c) fix, at supracompetitive levels, the price at which end-payors would pay for AndroGel.

215. The Agreements harmed Plaintiffs and the Class as set forth above.

216. The Agreements covered a sufficiently substantial percentage of the relevant market to harm competition.

217. There is and was no legitimate, nonpretextual, procompetitive justification for the payments from Solvay to Generic Defendants that outweighs its harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve such a purpose.

218. As a direct and proximate result of Defendants' anticompetitive conduct, as alleged herein, Plaintiffs and the Class were harmed as aforesaid.

219. By engaging in the foregoing conduct, Defendants entered a conspiracy and combination in restrain of trade in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class.

c. D.C. Code Ann. §§ 28-4503, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

e. Iowa Code § 553.3 *et seq.*, with respect to purchases of Lidoderm and AB-rated generic equivalents in Iowa by members of the Class.

f. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Class.

g. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class.

h. Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases in Maine by members of the Class.

i. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Class.

j. Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases in Minnesota by members of the Class.

k. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Class.

l. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by members of the Class.

m. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class.

n. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by members of the Class.

o. New York General Business Law § 340, *et seq.*, with respect to purchases in New York by members of the Class.

p. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

q. N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases in North Dakota by members of the Class.

r. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class.

s. 10 L.P.R.A. § 251, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

t. R.I. Gen. Laws §§ 6-36-7 *et seq.*, with respect to purchases in Rhode Island by members of the Class.

u. S.D. Codified Laws Ann. § 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by members of the Class.

v. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases in Utah by members of the Class.

w. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class.

x. Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

y. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by members of the Class.

z. Wis. Stat. § 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

CLAIM IV: ATTEMPTED MONOPOLIZATION UNDER STATE LAW (Asserted against Solvay)

220. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

221. This claim is pled as to Solvay.

222. Solvay, through its overarching anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Solvay's

conscious objective to control prices and/or exclude competition in the relevant market.

223. The natural and probable consequence of Solvay's overarching anticompetitive scheme, which was intended by, and plainly foreseeable to, Solvay, was to control prices and exclude competition in the relevant market, to the extent it did not succeed.

224. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Solvay would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

225. As a direct and proximate result of Solvay's illegal and monopolistic conduct, Plaintiffs and the Class were harmed as aforesaid.

226. By engaging in the foregoing conduct, Solvay has intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases in California by members of the Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

e. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class.

f. Iowa Code § 553.5 *et seq.*, with respect to purchases in Iowa by members of the Class.

g. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases in Maine by members of the Class.

h. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases in Michigan by members of the Class.

i. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

j. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Class.

k. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by members of the Class.

l. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class.

m. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by members of the Class.

n. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

o. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases in North Dakota by members of the Class.

p. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class.

q. 10 L.P.R.A. § 260, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

r. R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases in Rhode Island by members of the Class.

s. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by members of the Class.

t. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases in Utah by members of the Class.

u. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

v. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by members of the Class.

w. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

CLAIM V: UNJUST ENRICHMENT
(Asserted against All Defendants)

227. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

228. Defendants have benefited from the overcharges on their sales of AndroGel resulting from the unlawful and inequitable acts alleged in this Complaint.

229. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for AndroGel by Plaintiffs and members of the Class.

230. Plaintiffs and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges, to the economic detriment of Plaintiffs and the Class.

231. It would be futile for Plaintiffs and the Class to seek a remedy from any party with whom they had privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from Plaintiffs and the Class.

232. It would be futile for Plaintiffs and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased AndroGel, because those intermediaries are not liable and would not compensate Plaintiffs and the Class for Defendants' unlawful conduct or the harm caused to Plaintiffs and the Class by that unlawful conduct.

233. The economic benefit that Defendants derived by charging supracompetitive and artificially inflated prices for AndroGel is a direct and proximate result of Defendants' unlawful practices.

234. The financial benefits that Defendants derived rightfully belong to Plaintiffs and the Class, because Plaintiffs and the Class paid anticompetitive prices during the Class Period, inuring to the benefit of Defendants.

235. It would be inequitable under unjust enrichment principles under the laws of each of the States in the United States and the District of Columbia for the Defendants to be permitted to retain any of the overcharges for AndroGel derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

236. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiffs and the Class.

237. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiffs and the Class all unlawful or inequitable proceeds received by Defendants.

238. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff and the Class.

239. Plaintiffs and the Class have no adequate remedy at law.

CLAIM VI: DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 1 AND SECTION 2 OF THE SHERMAN ACT (Asserted against All Defendants)

240. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

241. Plaintiffs' allegations described herein and in the preceding Counts comprise violations of Sections 1 and 2 of the Sherman Act, in addition to the state laws supra.

242. Plaintiffs and the Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a) hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Sections 1 and 2 of the Sherman Act.

243. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

XIII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on behalf of themselves and the End-Payor Purchaser Classes, pray that the Court enter an order:

A. certifying the End-Payor Purchaser Classes pursuant to the Federal Rules of Civil Procedure, certifying Plaintiffs as the representatives of each Class, and designating their counsel as counsel for each Class;

B. declaring the Defendants' conduct to be in violation of the antitrust and/or deceptive practice statutes listed within this complaint;

C. granting Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

D. granting Plaintiffs and the Class injunctive relief sufficient to remove the barriers to generic entry in the AndroGel market erected by Defendants' anticompetitive conduct;

E. granting Plaintiffs and the Class damages as permitted by law;

F. granting Plaintiffs the right of disgorgement;

G. granting Plaintiffs and the Classes their costs of prosecuting this action, together with interest and reasonable attorneys' fees, experts' fees and costs; and

H. granting such other relief as this Court may deem just and proper.

XIV. JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Dated: August 5, 2014

Respectfully submitted,

s/Marshall P.Dees

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Counsel for End-Payor Class Plainitffs

CERTIFICATE OF SERVICE

The undersigned counsel for End-Payor Plaintiffs hereby certifies that on this 5th day of August, 2014, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to counsel of record.

Dated: August 5, 2014

/s/ Marshall P. Dees
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